

CHAPTER 33-09-03 CERTIFICATE OF NEED

Section

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33-09-03-01. Definitions. "Replacement equipment" means equipment which will be used instead of existing equipment which is documented to be obsolete, or not serviceable. Such equipment may be expected to possess expanded capabilities due to technical improvements but will not provide expansion into new health services.

History: Effective November 1, 1987; amended effective May 1, 1992.

General Authority: NDCC 23-01-03, 23-17.2-05

Law Implemented: NDCC 23-17.2-05

33-09-03-02. Notification of intent - Filing fee.

1. Each applicant shall submit a notification of intent on forms prescribed by the health council. Each notification of intent must be accompanied by a filing fee of seventy-five dollars payable to the North Dakota state department of health and consolidated laboratories.
2. The department, with concurrence of the health council, will determine purview.
3. The department will notify the applicant of the purview determination or seek additional information necessary to the determination of purview within fifteen working days of the receipt of a notification of intent. When appropriate, application forms prescribed by the health council will be sent to the applicant by the department.
4. Notifications of intent will expire one year following the mailing of the notice of the purview determination. In the case of any notification of intent deemed not subject to review, failure by the applicant to obligate funds for implementation of the proposal within the designated time will require the filing of a new notification of intent prior to implementation. In the case of any notification of intent deemed subject to review, failure by the applicant to complete the application form and to provide sufficient information to satisfy requirements to deem the application complete, as specified in subdivision b of subsection 1 of section 33-09-03-03, prior to

the expiration of the notification of intent will cause both the notification of intent and the application to expire.

History: Effective November 1, 1987; amended effective June 1, 1988.

General Authority: NDCC 23-01-03, 23-17.2-05

Law Implemented: NDCC 23-17.2-09

33-09-03-03. Types of review - Procedures.

1. **Full review.** A full review must be conducted of each proposal found subject under North Dakota Century Code section 23-17.2-03, unless the proposal is found eligible for a special review under provisions of subsection 2 of this section.
 - a. Completed applications must be submitted to the department. Each application must be accompanied by a fee payable to the North Dakota state department of health and consolidated laboratories as prescribed by North Dakota Century Code section 23-17.2-09.
 - b. Applications received with appropriate fee will be reviewed for completeness by the department within fifteen working days of receipt. Each application must address the state health plan, each of the criteria for review and each of the policy issues stated in section 33-09-03-04, and must include documentation of assertions found in the application. Submissions of requested additional information will be reviewed for completeness within fifteen working days of receipt. The department must deem the application complete or request necessary additional information from the applicant by the fifteenth working day. Such additional information must include documentation of assertions found in the application. No information may be required of an applicant which is not reasonably related to the state health plan, criteria for review, or policy issues specified in section 33-09-03-04 and necessary to perform review of the application.
 - c. Written notice that an application has been deemed complete will be provided to the applicant and must be published in one or more newspapers of general circulation within the affected service area. The notice must include:
 - (1) The name and address of the applicant, and a description of the proposal and its estimated costs.
 - (2) The proposed schedule for review.
 - (3) The time and manner by which affected persons may request an informal local hearing to provide additional information concerning the application.

- (4) The date of notice shall be the date of earliest publication or fourteen days following the date on which the application is deemed complete, whichever comes first.
- d. The department will have ninety days from the date of notice of completeness to conduct a review of the application based on criteria specified in section 33-09-03-04. The ninety-day-review period may be extended with concurrence of the applicant and the department. Recommendations of the department will be communicated to the applicant and to the health council.
- e. The health council may, at its option for the purpose of simultaneous consideration of like applications, delay consideration of certain applications. In such circumstances, the health council shall specify to the applicant a date certain by which the application will be considered. In no case will the health council cause consideration of any application to be delayed more than one hundred eighty days without the consent of the applicant.
- f. The health council will, except in cases described in subdivision e of subsection 1 of section 33-09-03-03, make its determination at the next scheduled meeting following completion of the department's review. The department will cause the determination and the basis for the determination to be communicated to the applicant in writing. This communication will be made within five working days of the date of determination. Written notice of the determination must be published in one or more newspapers of general circulation within the affected service area. The notice must include:
 - (1) The name and address of the applicant and a description of the proposal and its proposed costs.
 - (2) The determination of the health council.
 - (3) The time and manner by which affected persons may request a hearing conducted under North Dakota Century Code chapters 28-32 and 23-17.2 for reconsideration of the health council's determination.
 - (4) The manner in which additional information concerning the application or the reconsideration process may be obtained.
 - (5) Affected persons will have a minimum of fifteen days to respond following earliest publication of the notice.
- 2. **Special review.** The department may issue, but not deny, certificates of need for proposals which qualify. Special reviews will be conducted based on information obtained through the notification of intent form

and any supplemental information required by the department to verify qualification under the following circumstances:

- a. Emergency or circumstances beyond the control of the applicant.
- b. Elimination or prevention of imminent safety hazards as defined by federal, state, or local fire, building, or life safety codes, rules, or regulations.
- c. Compliance with state licensure, accreditation, or federal certification standards or building requirements for handicapped accessibility required to continue reimbursement for existing services under title XVIII or title XIX of the Social Security Act, or under North Dakota Century Code chapters 50-01 or 50-06.
- d. Cost overruns experienced in implementation of a proposal which exceed by ten percent or more the capital expenditure approved and specified in any certificate of need and which are not precipitated by a change in the scope of the project.
- e. Projects mandated by state law, with need established through the legislative process as indicated by the appropriation of funds for implementation.
- f. Acquisition and installation of replacement equipment if the equipment to be replaced meets applicable standards for minimum utilization adopted by the health council.
- g. Refinancing of existing debt which does not create additional capital except debt service reserve held in restricted capital accounts or capitalized costs of bondissuance.
- h. Proposals for the expansion of the physical plant of long-term care facilities which do not require a capital expenditure exceeding fifty thousand dollars and which do not facilitate the addition or expansion of services offered by the applicant.

History: Effective November 1, 1987; amended effective May 1, 1992; April 1, 1995.

General Authority: NDCC 23-01-03, 23-17.2-05

Law Implemented: NDCC 23-17.2-05

33-09-03-04. State health plan - Criteria for review - Policy issues. The health council will base its consideration of each application subject to full review on the department's review of the proposal and on the record of administrative proceedings held on the application. Complex applications may, at the discretion of the department, be divided into major components, each of which will be reviewed separately. Any such division will be communicated to the applicant as part of the notice of purview determination required by subsection 3 of section 33-09-03-02. Proposal modification or redefinition following the notice of purview determination,

but preceding the notice that an application has been deemed complete required by subdivision c of subsection 1 of section 33-09-03-03, may require change in the division of the application by the department. Any such change in division will be communicated to the applicant as part of the notice that the application has been deemed complete. If an application is subdivided for review by the department, the applicant may provide written notice to the department of preference that the application be considered in its entirety rather than its components. Such notice must include the applicant's rationale for preferring the consideration to be as a whole and must be received by the department within fifteen working days of the mailing date of the notice deeming the application complete. Pursuant to subsection 4 of North Dakota Century Code section 23-17.2-11, the health council may consider the application as a whole, by major components, or may condition the approval of an application in any other manner the council deems appropriate.

1. **Finding.** For each application or major component of an application, the health council must make a finding of consistent or inconsistent with the state health plan or any applicable document adopted by the health council as an addendum or appendix to the state health plan.
2. **Criteria for review.** The health council must make a finding of consistent, inconsistent, or not applicable for each of the following criteria, in relation to each application or major component of an application. An application or major component of the application must be found consistent with all criteria which are found applicable to the application in order to be approved by the health council.
 - a. The population served or to be served has a need for the services proposed to be offered or expanded based upon the following:
 - (1) Changes in the health needs of population within the identified service area.
 - (2) Unavailability of alternative existing facilities or resources.
 - (3) Obsolescence of existing facilities or equipment.
 - (4) Absence of adequate space or facilities to conduct a needed new or existing service.
 - (5) Requirement for recruitment of qualified personnel to respond to the needs of persons residing in the service area.
 - (6) Regulatory or accreditation requirements.
 - (7) Evidence that the proposal will reduce or prevent harm to the population intended to be served by the proposal.
 - b. Any additional costs incurred to implement a proposal which result in increased charges to the public will:

- (1) Provide improved access to needed services;
 - (2) Maintain access to needed services that would otherwise be lost; or
 - (3) Improve the value of needed services sufficiently to warrant the increased charges.
- c. The applicant has actively explored alternatives to the proposal including:
 - (1) Consideration of alternative uses of resources that may be more beneficial to the population intended to be served; and
 - (2) Consideration of the availability of less costly or more effective alternative means for providing the services to be offered, expanded, reduced, or relocated.
- 3. **Policy issues.** The health council must consider the following policies or practices and where appropriate may require adoption of such policies and practices as a condition for an approved certificate of need.
 - a. The proposed service or facility will contribute to meeting the health-related needs of persons or groups which have traditionally experienced difficulty in obtaining equal access to health services.
 - b. The resources including plant, personnel, appropriate ancillary or support services, and funds for acquisition and operation are sufficient to reasonably ensure compliance with applicable state licensing and federal certification requirements upon implementation of the proposal.
 - c. The application proposes special innovations in the financing of health services that may favorably affect the price of services proposed.
 - d. The application proposes special innovations in the delivery of health services that may improve patient access or patient outcome.
 - e. The proposed service or facility will address special circumstances or needs of health professional training programs or schools and health research programs located in the affected service area.

History: Effective November 1, 1987; amended effective May 1, 1992.

General Authority: NDCC 23-01-03, 23-17.2-05

Law Implemented: NDCC 23-17.2-05

33-09-03-05. Certificate of need expiration. Each certificate of need is valid for a period of one year from the date of determination. One extension of one hundred eighty days may be granted by the department upon request of the applicant. Failure by the applicant to obligate funds for implementation of the proposal within the designated time will render the certificate of need null and void. However, time spent in a reconsideration action or a court appeal will not count toward the expiration of a certificate of need.

History: Effective November 1, 1987.

General Authority: NDCC 23-01-03, 23-17.2-05

Law Implemented: NDCC 23-17.2-05